

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION**

VETSTEM, INC.,

Plaintiff,

vs.

INNOVATIONS MEDSPA, P.A.
d/b/a Innovations Physicians Services

(formerly d/b/a Innovations Medical
and formerly d/b/a Innovations
Medical Stem Cell Center),

Defendant.

CASE NO.:

ORIGINAL COMPLAINT

JURY TRIAL DEMANDED

Plaintiff VetStem, Inc. (“VetStem” or “Plaintiff”) files this Original Complaint against Defendant Innovations Medspa, P.A. alleging as follows:

THE PARTIES

1. VetStem is a corporation organized and existing under the laws of Delaware having a principal place of business at 14261 Danielson Court, Poway, California 92064.

2. Defendant Innovations Medspa, P.A. (“Innovations Medical” or “Defendant”) is a corporation organized and existing under the laws of Texas, having a principal place of business at 12660 Coit Road, Suite 100, Dallas, Texas 75251. Innovations Medspa, P.A. operates under the trade name of “Innovations Medical.” Innovations Medical also maintains a regular and established place of business at 1650 West Rosedale Street, Suite 101, Fort Worth, Texas 76104. Innovations Medical may be served with process through its registered agent Dr. Bill J. Johnson at 12660 Coit Road, Suite 100, Dallas, Texas 75251.

JURISDICTION AND VENUE

3. This is a patent infringement action under 35 U.S.C. § 271, *et seq.*

4. This Court has jurisdiction to hear these matters, as this Court has exclusive subject matter jurisdiction over patent infringement causes of action arising under 28 U.S.C. §§ 1331, 1338(a).

5. Innovations Medical is a Texas professional association that operates two office locations within this District. Innovations Medical maintains a regular and established place of business at 1650 West Rosedale Street, Suite 101, Fort Worth, Texas 76104. Additionally, Innovations Medical maintains a regular and established place of business at 12660 Coit Road, Suite 100, Dallas, Texas 75251. Innovations Medical offers for sale, sells, and performs the accused regenerative stem cell therapies from these locations. VetStem's claims of patent infringement against Innovations Medical arise from these infringing acts.

6. Personal jurisdiction exists and venue is proper in this Court under 28 U.S.C. §§ 1391(b), (c), and 1400(b).

BACKGROUND AND FACTS

7. Dr. Bob Harman, D.V.M., M.P.V.M., is a licensed veterinarian with over thirty years of experience as a chief executive officer and biotechnology entrepreneur. Dr. Harman has founded and managed several successful biotechnology businesses — including VetStem and Personalized Stem Cells, Inc. Dr. Harman has also overseen the completion of more than 1,000 contract research projects for the development of veterinary and human biotechnology products. Among these research projects are studies directed to the effectiveness of cell populations comprising adipose-derived mesenchymal stem cells for the treatment of osteoarthritis in canines. The results of these studies, and others, have been published in peer-reviewed research publications dating as far back as 2007.

1 8. In 2002, Dr. Harman co-founded VetStem for the purpose of offering new
2 hope for animals suffering from debilitating diseases and life-altering injuries. VetStem
3 is veterinarian-led and is focused on exploring regenerative modalities including, by
4 way of example, stem cell therapies. Dr. Harman serves as the Chief Executive Officer
5 of VetStem. Since its founding, VetStem has performed stem cell treatments to treat
6 over 16,000 animals, becoming the world-leader in regenerative veterinary medicine
7 services. VetStem's laboratory services has delivered stem cell treatments to over 2,400
8 veterinarians across the United States.

9 9. Dr. Harman has also spearheaded innovative research into therapeutic uses
10 of adipose-derived stem cells in human applications. In October 2018, Dr. Harman co-
11 founded Personalized Stem Cells, Inc. ("PSC"), a Delaware corporation having its
12 principal place of business in Poway, California. PSC is an affiliate of VetStem
13 operating under license to the VetStem Patents. PSC conducts studies for the purpose
14 of developing and studying therapeutic treatments of various afflictions in humans
15 using adipose derived stem cells. VetStem has contracted with PSC to provide stem
16 cell lab services for use in studies conducted by PSC.

17 10. Additionally, VetStem has established research relationships with other
18 prominent veterinarians and research institutions. VetStem is the exclusive licensee of
19 over 50 patents held by the University of Pittsburg, the University of California, and
20 Artecetel, Inc. relating to use of adipose-derived stem cells.

21 11. VetStem's extensive research into regenerative stem cell treatments
22 employing adipose-derived stem cells has yielded three validly issued U.S. Patents, to
23 date. Among these are VetStem's U.S. Pat. No. 9,453,202 ("the '202 Patent") and U.S.
24 Pat. No. 11,129,855 ("the '855 Patent"). Each is entitled "Methods of Preparing and
25 Using Novel Stem Cell Compositions and Kits Comprising the Same." They disclose
26 and claim, respectively, certain novel treatment methods utilizing cell populations
27 comprising adipose-derived stem cells.

28 **THE ASSERTED PATENTS AND TECHNOLOGY**

1 12. On September 27, 2016, United States Patent No. 9,453,202 was duly and
2 legally issued for “Methods of Preparing and Using Novel Stem Cell Compositions and
3 Kits Comprising the Same.” As of the filing of this Complaint, the ‘202 Patent remains
4 in force. A true and correct copy of the ‘202 Patent is attached hereto as Exhibit A and
5 made a part hereof.

6 13. The application issuing as the ‘202 Patent was originally filed on October
7 7, 2004. It claims priority to four earlier filed provisional patent applications, including
8 Provisional Application Ser. No. 60/510,021, filed on Oct. 8, 2003, Provisional
9 Application Ser. No. 60/510,022, filed on Oct. 8, 2003, Provisional Application Ser.
10 No. 60/509,928, filed on Oct. 8, 2003, and Provisional Application Ser. No. 60/510,072,
11 filed on Oct. 8, 2003. The ‘202 Patent issued on September 27, 2016 following lengthy
12 prosecution that resulted in the term of the ‘202 Patent being extended by 1173 days
13 under 35 USC 154(b).

14 14. The ‘855 Patent was duly and legally issued on September 28, 2021, and
15 is entitled “Methods of Preparing and Using Novel Stem Cell Compositions and Kits
16 Comprising the Same.” As of the filing of this Complaint, the ‘855 Patent remains in
17 force. A true and correct copy of the ‘855 Patent is attached hereto as Exhibit B and
18 made a part hereof. The application issuing as the ‘855 Patent was originally filed on
19 April 27, 2020. It claims priority to the application issuing as the ‘202 Patent, and to the
20 four provisional patent applications filed on Oct. 8, 2003. The ‘855 Patent shares a
21 common specification with the ‘202 Patent.

22 15. The ‘202 Patent and the ‘855 Patent are referred to collectively, herein, as
23 the “Asserted Patents” or the “Patents-in-Suit.”

24 16. VetStem is the owner of all rights, title, and interest in the Asserted Patents
25 — including all rights to enforce, prosecute, and collect damages for infringement
26 thereof. Accordingly, VetStem possesses the exclusive right and standing to bring the
27 present action for Innovations Medical’s infringement of claims of the Asserted Patents,
28 detailed herein.

1 17. The '202 Patent discloses and claims methods of treating inflammation at
2 the site of a musculoskeletal injury or disease in both human and veterinary settings.
3 The treatments utilize a cell population comprising stem cells obtained from adipose
4 tissue (fat) harvested from the person or animal to be treated. The adipose tissue is
5 processed to release and separate the cell population comprising stem cells from
6 surrounding adipose tissue. Although the '202 Patent discloses and claims several
7 alternative processing steps for both releasing and separating the cell population from
8 the adipose tissue, this processing is typically done via enzymatic digestion followed
9 by centrifugation. Once released and separated, the cell population comprising adipose
10 derived stem cells is not subjected to additional processing to further isolate the stem
11 cells from other cells within the cell population. Rather, according to the methods
12 claimed in the '202 Patent, the cell population is then reintroduced into the patient
13 directly at the site of a musculoskeletal injury or disease to treat inflammation.

14 18. The streamlined processing methodology claimed in the '202 Patent,
15 which does not involve subsequent processing to isolate, culture, or expand the stem
16 cell component of the cell population, ran counter to the prevailing thought and practice
17 in the industry at the time of the '202 Patent application filing. At that time, stem cell
18 therapies utilized cell populations comprising expanded stem cell populations obtained
19 through costly and time-consuming rounds of culturing. Dr. Harman discovered that
20 treatment with cell populations that have not been subjected to these further expansion
21 and culturing steps are therapeutically superior, far less costly, and obtainable in far less
22 time.

23 19. VetStem offers, sells, and performs therapies practicing the inventions
24 claimed in the '202 Patent on animals. Likewise, VetStem's affiliate PSC also offers,
25 sells, and performs therapies practicing the inventions claimed in the '202 Patent on
26 human.

27 20. Because the '855 Patent is within the same patent family as the '202 Patent
28 and shares a common specification, it discloses identical subject matter to that disclosed

1 in the ‘202 Patent. The claims of the ‘855 Patent are more broadly addressed to
2 treatment methods utilizing a cell population comprising stem cells obtained via
3 processing steps to release and separate the cell population from surrounding adipose
4 tissue. Again, as claimed in the ‘855 Patent, this processing is devoid of any further
5 steps to further isolate the stem cells contained therein from other cells released and
6 separated from the adipose tissue. This cell population is then provided to the patient to
7 treat an injury or disease afflicting the patient.

8 21. Importantly, the ‘202 and ‘855 Patents comprise only method claims.
9 Therefore, VetStem is under no obligation to “mark” its products and services practicing
10 any claim of the Asserted Patents under 35 U.S.C. § 287, *et seq.* Further, licensees to
11 the Asserted Patents are also not obligated to mark their licensed products and services.

12 22. The ‘202 Patent has been in force for the duration of Innovations Medical’s
13 infringing activities over the past six years. Therefore, VetStem is entitled to damages
14 for the entire period thereof.

15 **INNOVATIONS MEDICAL’S INFRINGING STEM CELL THERAPIES**

16 23. Defendant Innovations Medical operates two clinics in north Texas from
17 which it commercially offers for sale, sells, and performs regenerative therapies
18 utilizing cell populations comprising adipose-derived stem cells to treat various
19 ailments afflicting its patients. More specifically, Innovations Medical offers, sells, and
20 performs “Stem Cell Therap[ies]” that are described as “us[ing] the body’s own
21 regenerative properties to fight aging, treat disease, and even improve your
22 appearance.”¹

23 24. Innovations Medical touts on its website that it “has performed stem cell
24 treatments in North Texas since 2013” and that “[t]ogether with the Cell Surgical
25 Network, we have performed more than 14,000 treatments.” Innovations Medical
26
27

28 ¹ See, Innovation Medical website at URL: <https://innovationsmedical.com/stem-cell-therapy/>

1 identifies itself as “proud to be the first Cell Surgical member in North Texas.”² The
2 Innovations Medical website includes hyperlinks to Cell Surgical Network’s (“CSN”)
3 website. Additionally, Innovations Medical cites CSN’s stem cell treatment protocols,
4 studies, and patient outcome statistics throughout its website.

5 25. Innovations Medical’s Stem Cell Therapies are promoted for treatment of
6 several musculoskeletal injuries and disorders, including arthritis, knee pain, meniscus
7 tears, muscle injuries, tendon injuries, and ligament injuries.³ Innovations Medical’s
8 Stem Cell Therapies involve injection of cell populations comprising adipose derived
9 stem cells (which Innovations Medical sometimes refers to as “Stromal Vascular
10 Fraction” or “SVF”) directly into the joint, muscle, tendon, or ligament being treated.
11 Other conditions are treated via direct injection and/or intravenous deployment,
12 including neurological conditions, autoimmune diseases, heart disease, urologic
13 conditions, kidney and bladder conditions, vascular disease, and lung diseases, among
14 others.

15 26. Innovations Medical harvests fat (adipose tissue) from the patient’s body,
16 from which the “SVF” is extracted via processing steps that include centrifugation
17 following incubation of the fat in an enzyme. This processing releases and separates the
18 SVF cell population comprising adipose stem cells, growth factors, and other cells from
19 the adipose tissue.⁴ SVF is then reintroduced into the patient’s body to effect treatment.

20 27. Innovations Medical is an Affiliate within the Cell Surgical Network
21 (“CSN”).⁵ CSN is a corporation organized and existing under the laws of California.

22
23 ² See, Innovations Medical website at URL: <https://innovationsmedical.com/for-physicians/stem-cell-harvesting/>. See, also, URL: <https://innovationsmedical.com/for-physicians/> (“we have performed
24 more than 800 adipose-derived stem cell procedures”)

25 ³ See, Innovations Medical website at URL: <https://innovationsmedical.com/stem-cell-therapy/musculoskeletal-injuries/>

26 ⁴ See, Innovations Medical website at URL: <https://innovationsmedical.com/adipose-derived-stem-cells/>
27

28 ⁵ Innovations Medical admits to being an Affiliate of CSN on its website, as noted above in para. 24 of this Complaint. Additionally, Innovations Medical and its founding physician, Dr. Bill Johnson, are identified as participants performing CSN’s stem cell procedures using the CSN Time Machine system

1 CSN purports to operate a “medical network” for “the investigational use of Adipose
2 Derived Stem Cells (ADSC’s) for clinical research and deployment.” CSN’s medical
3 network comprises several “Affiliate” clinics that offer for sale, sell, and perform
4 regenerative stem cell procedures promoted by CSN in accordance with specific
5 protocols and equipment provided by CSN. The CSN protocol is marketed as the CSN
6 Time Machine system. Exh. C at 1.

7 28. VetStem has alleged infringement of the claims of its ‘202 Patent through
8 use of the CSN Time Machine system and protocol for treatment of musculoskeletal
9 injuries and diseases in another, recently concluded litigation against another CSN
10 Affiliate. In particular, VetStem alleged infringement of at least claim 1 of the ‘202
11 Patent by California Stem Cell Treatment Center, Inc. (“CSCTC”) relating to CSCTC’s
12 selling and performing stem cell therapies in accordance with the CSN Time Machine
13 system and protocol to treat musculoskeletal injuries and diseases.⁶

14 29. During the CSCTC Litigation, the District Court found, as a matter of law
15 on summary judgment, that use of the CSN Time Machine system and treatment
16 protocol for treatment of musculoskeletal injuries and diseases infringed claims of the
17 ‘202 Patent. *See*, Exh. D (Plaintiff’s Memorandum of Contentions of Fact and Law
18 [Dkt. 229] submitted in the CSCTC Litigation). Innovations Medical utilizes the same
19 CSN Time Machine system and treatment protocol to perform its accused Stem Cell
20 Treatments.

21 30. Use of the CSN Time Machine system and treatment protocol by
22 Innovations Medical is confirmed by the CSN article attached hereto as Exhibit C,
23 which describes aspects of the CSN Time Machine system and identifies Innovations
24 Medical and Dr. Bill Johnson as contributors.

25 _____
26 and protocols and contributing data to CSN’s article entitled, *A Prospective Safety Study of Autologous*
27 *Adipose-Derived Stromal Vascular Fraction Using a Specialized Surgical Processing System*,
published in 2017. *See* Exh. C at 1, 4.

28 ⁶ *VetStem, Inc. v. Cal. Stem Cell Treatment Center, Inc.*, Case No. 2:19-CV-4728-AB, filed in the
Central District of California, Western Division (“the CSCTC Litigation”).

1 31. Aspects of CSN’s infringing protocols are memorialized in the CSN study
2 article, including a description of the equipment and processing steps for collecting
3 adipose tissue from a patient and obtaining a cell population comprising adipose stem
4 cells (referred to as “SVF” in CSN’s documents). *See generally* Exhibit C. Specifically,
5 the article describes processing steps including enzymatic digestion of adipose tissue
6 followed by centrifugation to separate the SVF cell population. In application for
7 treatment of musculoskeletal conditions, such as arthritis of the knee, for example, the
8 prepared SVF is injected directly to the site of the musculoskeletal injury or disease to
9 reduce inflammation present at the site.

10 32. CSN Affiliate clinics and physicians are required to purchase CSN’s Time
11 Machine equipment and to adhere to CSN’s protocols for operating the Time Machine
12 to produce SVF and for therapeutic deployment of the SVF to treat patients.⁷

13 33. Based on CSN’s requirements in how Affiliates must operate the Time
14 Machine equipment and processes, CSN’s Affiliates have already been effectively
15 adjudicated to infringe at least the ‘202 Patent based on their performance of CSN’s
16 instructions and treatment procedures. By way of example, the California Stem Cell
17 Treatment Center, Inc. (“CSCTC”) is an Affiliate clinic within CSN.

18 34. Innovations Medical has commercially offered and performed
19 regenerative adipose derived stem cell therapies in human patients from its two clinics
20 within this District since at least 2013. Innovations Medical’s principal physician is Dr.
21 Bill Johnson.

22 35. Innovations Medical admits to being an Affiliate within the Cell Surgical
23 Network, affirming on its website that “[t]ogether with the Cell Surgical Network, we
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26
27 ⁷ See Original Complaint at 5–6, *United States v. Cal. Stem Cell Treatment Center, Inc.*, 624 F. Supp.
28 3d 1177 (C.D. Cal. 2022) (No. 5:18-CV-1005); *see also* Memorandum in Opposition to Plaintiff’s
Motion for Summary Judgment at 29, *United States v. Cal. Stem Cell Treatment Center, Inc.*, 624 F.
Supp. 3d 1177 (C.D. Cal. 2022) (No. 5:18-CV-1005).

1 have performed more than 12,000 treatments and [we] are proud to be the first Cell
2 Surgical member in North Texas.”⁸

3 36. Upon information and belief, Innovations Medical utilizes the same,
4 infringing regenerative stem cell therapy protocols employed by all CSN Affiliates,
5 which are the same protocols that have been found to infringe VetStem’s patent rights
6 as a matter of law. Specifically, Innovations Medical offers and performs regenerative
7 stem cell therapies at its clinics, during which fat (adipose tissue) is harvested from a
8 patient as lipoaspirate via a liposuction procedure. The lipoaspirate is then treated with
9 an enzyme to effectuate enzymatic digestion, thereby releasing a cell population
10 comprising SVF, wherein the SVF comprises a heterogeneous mixture of adult
11 mesenchymal stem cells and several other types of cells and growth factors.
12 Centrifugation is then used to separate the released SVF from the surrounding adipose
13 tissue. Once separated, the SVF is injected directly into the site of the musculoskeletal
14 injury or disease in the patient to treat the inflammation at the site of the musculoskeletal
15 injury or disease.⁹

16 37. The Abstract of the study article entitled “Safety of Stromal Vascular
17 Fraction Cells Applications in Chronic Pain” provides the following description of the
18 protocol employed by CSN Affiliates (including by Innovations Medical) and the
19 results achieved:

20 Autologous stromal vascular fraction (SVF) can be ***enzymatically released***
21 ***from lipoaspirate*** obtained under local anesthesia. SVF is known to have
22 regenerative, ***anti-inflammatory***, pain mitigating, and immune-
23 modulatory properties. Our translational research network has been
24 studying the safety and efficacy of SVF since 2012. Almost 100 related
25 physician teams around the world are applying the same institutional
26 review board-approved methods of SVF production, which use a surgically
closed SVF isolation system. ***During the same outpatient surgical***
procedure, procured SVF is administered according to strict investigative

27 ⁸ See Innovations Medical website at URL: <https://innovationsmedical.com/stem-cell-therapy/>.

28 ⁹ See Innovations Medical website at URL: <https://innovationsmedical.com/stem-cell-therapy/musculoskeletal-injuries/>

1 protocols to mitigate diseases associated with chronic pain including
 2 arthritis, autoimmune disease, neurodegenerative disease, and various
 3 inflammatory conditions. The shared research collaborative online
 4 database contains safety and efficacy data on more than 3500 patients. ***Our***
 5 ***processed SVF contains valuable cytokine growth factors in addition to***
 6 ***both adult mesenchymal and hematopoietic stem cells targeting***
 7 ***damaged, or inflamed tissue.*** SVF administration may potentially play a
 large role in the outpatient treatment of pain. In this article, we describe
 our protocol for the production and administration of SVF, and its safety
 and efficacy in the treatment of pain associated with chronic conditions.

8 See Landar, MD et al., *Safety of Stromal Vascular Fraction Cells Applications in*
 9 *Chronic Pain* (2016) (emphasis added) (attached hereto as Exhibit D).

10 38. Innovations Medical's performance of the CSN's Time Machine system
 11 and treatment protocol practices the inventions claimed in one or more claims of the
 12 '202 and '885 Patents. Such performance constitutes a patented use of a composition of
 13 matter (e.g., claimed methods of obtaining and using a cell population comprising
 14 adipose derived stem cells to effect treatment). Such use directly causes a therapeutic
 15 effect, such as the treatment of inflammation occurring at a site of a musculoskeletal
 16 injury or disease of the patient.

17 39. Importantly, like CSN, Innovations Medical is not operating under any
 18 formal study sanctioned by the Food and Drug Administration for the purpose of
 19 developing a new drug or device. This is evidenced by Innovations Medical's own
 20 website:

21 The Cell Surgical Network and its affiliate treatment centers are not
 22 offering stem cell therapy as a cure for any condition, disease, or injury.
 23 No statements or implied treatments on this website have been evaluated
 24 or approved by the FDA. This website contains no medical advice. All
 25 statements and opinions provided by this website are provided for
 26 educational and informational purposes only and we do not diagnose or
 27 treat via this website or via telephone. ***The Cell Surgical Network and its***
 28 ***affiliate treatment centers are offering patient funded research to***
provide individual patients with Stromal Vascular Fraction that contains
their own autologous stem cells and growth factors and the treatment

1 *centers provide surgical procedures only and are not involved in the use*
2 *or manufacture of any investigational drugs.*

3 The Cell Surgical network does not claim that any applications, or
4 potential applications, using autologous stem cells are approved by the
5 FDA, or are even effective. We do not claim that these treatments work for
6 any listed nor unlisted condition, intended or implied. It's important for
7 potential patients to do their own research based on the options that we
8 present so that one can make an informed decision. Any decision to
9 participate in our patient funded experimental protocols is completely
10 voluntary.¹⁰

11 40. During the pendency of the CSCTC Litigation, VetStem caused its counsel
12 to send direct correspondence to Innovations Medical's registered agent and principal
13 physician, Dr. Bill J. Johnson, at both of its clinic locations in January of 2022. This
14 correspondence provided actual notice to Innovations Medical of VetStem's claims of
15 patent infringement—and further invited Innovations Medical to engage VetStem in
16 discussions on how to amicably resolve the present dispute. The January 2022
17 correspondence detailed the many claims VetStem has against Innovations Medical,
18 which are substantially the same as those presented herein. The January 2022
19 correspondence also included citations to findings made and orders entered by the Court
20 in the CSCTC Litigation affirming VetStem's claims of infringement and rejecting
21 CSCTC's defenses. VetStem's letter was ignored by Innovations Medical. Since that
22 time, and presently, Innovations Medical has continued to willfully infringe VetStem's
23 patent rights. Accordingly, VetStem was forced to file the present lawsuit.

24 41. Upon information and belief, Innovations Medical was aware of the
25 VetStem Patents, as well as the infringing nature of its conduct, much earlier than
26 January of 2022. As mentioned above, VetStem has asserted its patents against other
27 CSN affiliates for practicing the same infringing protocols that Innovations Medical
28 practices. CSN and its founders, Drs. Berman and Lander, regularly communicate with

¹⁰ See Innovations Medical website at URL: <https://innovationsmedical.com/fda-disclaimer/>
(emphasis added).

1 its Affiliates with regard to the protocols it promotes, to include providing updates on
2 litigations challenging the use of those protocols filed by the FDA and by VetStem.
3 Therefore, upon information and belief, Innovations Medical learned of the VetStem
4 Patents, as well as the infringing nature of its own conduct, by way of CSN's inter-
5 network communications, inter-network conferences, and/or word of mouth in relation
6 to discussions of VetStem's enforcement actions against other CSN Affiliates.

7 **COUNT I**

8 **Infringement of U.S. Patent No. 9,453,202 by Innovations Medical**

9 42. VetStem repeats and realleges the preceding paragraphs as if fully set forth
10 herein.

11 43. Innovations Medical, without authority, consent, right or license, offers for
12 sale, sells, and/or performs Stem Cell Therapies for the treatment of various conditions
13 and diseases that practice the invention claimed in at least claim 1 of the '202 Patent.

14 44. Innovations Medical's offering for sale, selling, and/or performing its Stem
15 Cell Therapies to treat musculoskeletal injuries and diseases, including arthritis, knee
16 pain, meniscus tears, muscle injuries, tendon injuries, and ligament injuries, among
17 others, directly infringes at least claim 1 of the '202 Patent. Innovations Medical is
18 therefore liable for direct infringement, either literally or under the doctrine of
19 equivalents, of the '202 Patent pursuant to 35 U.S.C. § 271(a) by at least following the
20 procedures described by CSN's requirements of its Affiliates.

21 45. Innovations Medical's physicians, personnel, representatives, affiliates,
22 and/or agents perform its regenerative stem cell therapies to effect treatment on human
23 patients.

24 46. More specifically, Innovations Medical's physicians and/or personnel
25 collect adipose tissue from the patient through tumescent liposuction, during which the
26 adipose tissue is repeatedly scraped using a cannula to slice and cut away small pieces
27 of adipose tissue for removal.
28

1 47. The harvested lipoaspirate comprising adipose tissue is further processed
2 by Innovations Medical's physicians and/or personnel to prepare cell population
3 comprising stem cells from the adipose tissue, which Innovations Medical (and CSN)
4 refer to as "SVF."

5 48. The processing steps include, first, incubating the harvested adipose tissue
6 with an enzyme resulting in enzymatic digestion of the adipose tissue to release the cell
7 population therein, comprising stem cells and growth factors, from within the
8 lipoaspirate.

9 49. Thereafter, the released cell population undergoes centrifugation to
10 separate the cell population (which Innovations Medical and CSN refer to as "SVF")
11 from the digested adipose tissue. The resulting cell population comprises stem cells and
12 growth factors, among other cell types.

13 50. The cell population is loaded into one or more syringes for injection into
14 the patient without any further processing being performed to further isolate the stem
15 cells from the other cells separated from the adipose tissue.

16 51. For treatment of musculoskeletal conditions, the cell population is
17 deployed via direct injection into the patient at the joint, bone, cartilage, ligament,
18 tendon, bursa, or muscle at which the musculoskeletal condition or disease is present.
19 These stem cell treatments are promoted by Innovations Medical to reduce
20 inflammation and relieve pain resulting from the musculoskeletal condition or disease
21 at the injection site.

22 52. Performance of its Stem Cell Therapies to treat musculoskeletal injuries
23 and diseases by Innovations Medical in this manner constitutes direct infringement of
24 at least claim 1 of the '202 Patent.

25 53. Such performance constitutes the practice of a patented use of a
26 composition of matter in violation of at least claim 1 of the '202 Patent, which has been
27 found to be a biotechnology patent for purposes of application of 35 USC 287(c).
28

1 54. Innovations Medical's Stem Cell Therapies are offered commercially and
2 for profit to patients, are paid for commercially by the patients, and are not solely for
3 uses reasonably related to the development and submission of information for testing to
4 obtain approval from the Food and Drug Administration.

5 55. VetStem expressly reserves the right to assert additional claims of the '202
6 Patent against Innovations Medical.

7 56. VetStem has been damaged as a result of Innovations Medical's infringing
8 conduct. Innovations Medical is, thus, liable to VetStem in an amount that adequately
9 compensates for their infringement, which, by law, cannot be less than a reasonable
10 royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

11 57. Since January 7, 2022, if not earlier, Innovations Medical has been aware
12 of the specific claims of patent infringement made herein. On that date, counsel for
13 VetStem sent correspondence addressed to both Innovations Medical locations
14 apprising Innovations Medical of VetStem's patent rights and of VetStem's claims of
15 infringement against Innovations Medical. This correspondence was addressed to
16 Innovations Medical's registered agent and principal physician—Dr. Bill J. Johnson.
17 Accordingly, Innovations Medical has had actual notice of the infringement claims
18 presented herein for two years. In that time, Innovations Medical has refused to agree
19 to any amicable licensing solution proposed by VetStem.

20 58. Based on Innovations Medical's actual knowledge of the '202 Patent and
21 specific knowledge of VetStem's infringement claims presented herein, in addition to
22 Innovations Medical's objective recklessness in continuing to make, use, and sell its
23 regenerative stem cell therapies after receipt of VetStem's notice letter, Innovations
24 Medical's infringement of the '202 Patent has been willful since at least January 7,
25 2022. Therefore, VetStem is further entitled to enhanced damages under 35 U.S.C.
26 § 284.

COUNT II

Infringement of U.S. Patent No. 11,129,855 by Innovations Medical

59. VetStem repeats and realleges the preceding paragraphs as if fully set forth herein.

60. Innovations Medical, without authority, consent, right or license, offers for sale, sells, and/or performs Stem Cell Therapies for the treatment of various conditions and diseases that practice the invention claimed in at least claim 1 of the ‘855 Patent.

61. Innovations Medical’s offering for sale, selling, and/or performing its Stem Cell Therapies to treat musculoskeletal injuries and diseases, neurological conditions, autoimmune diseases, heart disease, urologic conditions, kidney and bladder conditions, vascular disease, and lung diseases, among others, directly infringes at least claim 1 of the ‘855 Patent. Innovations Medical is therefore liable for direct infringement, either literally or under the doctrine of equivalents, of the ‘855 Patent pursuant to 35 U.S.C. § 271(a) by at least following the procedures described by CSN’s requirements of its Affiliates.

62. Innovations Medical’s physicians, personnel, representatives, affiliates, and/or agents perform its development of cell populations and its regenerative stem cell therapies to effect treatment on human patients.

63. More specifically, Innovations Medical’s physicians and/or personnel collect adipose tissue from the patient through tumescent liposuction, during which the adipose tissue is repeatedly scraped using a cannula to slice and cut away small pieces of adipose tissue for removal.

64. The harvested lipoaspirate comprising adipose tissue is further processed by Innovations Medical’s physicians and/or personnel to prepare cell population comprising stem cells from the adipose tissue, which Innovations Medical (and CSN) refer to as “SVF.”

65. The processing steps include, first, incubating the harvested adipose tissue with an enzyme resulting in enzymatic digestion of the adipose tissue to release the cell

1 population therein, comprising stem cells and growth factors, from within the
2 lipoaspirate.

3 66. Thereafter, the released cell population undergoes centrifugation to
4 separate the cell population (which Innovations Medical and CSN refer to as “SVF”)
5 from the digested adipose tissue. The resulting cell population comprises stem cells and
6 growth factors, among other cell types.

7 67. The cell population is loaded into one or more syringes for injection into
8 the patient without any further processing being performed to further isolate the stem
9 cells from the other cells separated from the adipose tissue.

10 68. Innovation Medical’s preparation and use of its regenerative stem cell
11 therapies in this manner constitutes direct infringement of at least claim 1 of the ‘855
12 Patent.

13 69. Such performance constitutes the practice of a patented use of a
14 composition of matter in violation of at least claim 1 of the ‘855 Patent, which, like the
15 ‘202 Patent, is a biotechnology patent for purposes of application of 35 USC 287(c).

16 70. Innovations Medical’s Stem Cell Therapies are offered commercially and
17 for profit to patients, are paid for commercially by the patients, and are not solely for
18 uses reasonably related to the development and submission of information for testing to
19 obtain approval from the Food and Drug Administration.

20 71. VetStem expressly reserves the right to assert additional claims of the ‘855
21 Patent against Innovations Medical.

22 72. VetStem has been damaged as a result of Innovations Medical’s infringing
23 conduct. Innovations Medical is, thus, liable to VetStem in an amount that adequately
24 compensates for their infringement, which, by law, cannot be less than a reasonable
25 royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

26 73. Since January 7, 2022, if not earlier, Innovations Medical has been aware
27 of the specific claims of patent infringement made herein. On that date, counsel for
28 VetStem sent correspondence addressed to both Innovations Medical locations

1 apprising Innovations Medical of VetStem's patent rights and of VetStem's claims of
2 infringement against Innovations Medical. This correspondence was addressed to
3 Innovations Medical's registered agent and principal physician—Dr. Bill J. Johnson.
4 Accordingly, Innovations Medical has had actual notice of the infringement claims
5 presented herein for two years. In that time, Innovations Medical has refused to agree
6 to any amicable licensing solution proposed by VetStem.

7 74. Based on Innovations Medical's actual knowledge of the '855 Patent and
8 specific knowledge of VetStem's infringement claims presented herein, in addition to
9 Innovations Medical's objective recklessness in continuing to make, use, and sell its
10 regenerative stem cell therapies after receipt of VetStem's notice letter, Innovations
11 Medical's infringement of the '855 Patent has been willful since at least January 7,
12 2022. Therefore, VetStem is further entitled to enhanced damages under 35 U.S.C.
13 § 284.

14 **JURY DEMAND**

15 VetStem hereby requests a trial by jury pursuant to Rule 38 of the Federal Rules
16 of Civil Procedure.

17 **PRAYER FOR RELIEF**

18 VetStem requests that the Court find in its favor and against Innovations Medical,
19 and that the Court grant VetStem the following relief:

20 a. Judgment that one or more claims of the '202 and '855 Patents have been
21 infringed, either literally and/or under the doctrine of equivalents, by Innovations
22 Medical;

23 b. Judgment that Innovations Medical accounts for and pay to VetStem all
24 damages to and costs incurred by VetStem because of Innovations Medical's infringing
25 activities;

26 c. Judgement that Innovations Medical's infringement is willful from the
27 time Innovations Medical became aware of the infringing nature of its products and
28

1 services and that the Court award treble damages for the period of such willful
2 infringement pursuant to 35 U.S.C. § 284;

3 d. That VetStem be granted pre-judgment and post-judgment interest on the
4 damages caused by Innovations Medical's infringing activities and other conduct
5 complained of herein;

6 e. That the Court declare this an exceptional case and award VetStem its
7 reasonable attorney's fees and costs in accordance with 35 U.S.C. § 285;

8 f. That Innovations Medical, its officers, agents, servants and employees, and
9 those persons in active concert and participation with any of them, be permanently
10 enjoined from infringement of one or more claims of the '202 and '855 Patents by the
11 acts complained of herein. In the alternative, if the Court finds that an injunction is not
12 warranted, VetStem requests an award of post judgment royalty to compensate for
13 future infringement; and

14 g. That VetStem be granted such other and further relief as the Court may
15 deem just and proper under the circumstances.

16
17 DATED: January 12, 2024

/s/ Jonathan T. Suder

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